**AUB KQ1 Evidence Table (Reference ID #1431)**

| **Study Description** | **Intervention(s)/ Comparator(s)** | **Patient Population** | **Baseline Measure(s)a** |  **Outcome Measure(s)** | **Overall Quality****Risk of Bias** |
| --- | --- | --- | --- | --- | --- |
| **Author:**Elkind-Hirsch et al., 2008**Country:**United States**Enrollment** **period:** August 2006 to June 2007**Intervention** **setting:** Outpatient clinics**Funding:**Amylin Pharmaceuticals, Inc/Eli Lilly Corp **Author industry relationship disclosures:**2/5**Study Design:** RCT**Blinding:** None | **Intervention:**Exenatide 5 µg by subcutaneous injection twice a day and increased to 10 µg twice per day after 1 month.**Comparator:**Metformin 500 mg for two weeks and gradually increased to 1000 mg twice a day;Combination: metformin 500 mg for two weeks and gradually increased to 1000 mg twice a day plus exenatide 5 µg by subcutaneous injection twice a day and increased to 10 µg twice per day after 1 month.All groups received treatment for 24 weeks.**Groups:****G1:** Exenatide**G2:** Metformin**G3:** Combination metformin and exenatide**Followup:**24 weeks | **Inclusion criteria:** Aged 18 to 40 yearsPolycystic ovary syndromeOverweight/obese (BMI >27)Menstrual disorders (fewer than six menstruations in 12 months)One of the following two criteria:either clinical and/or biochemical hyperandrogenism(excluding secondary causes) and/or polycystic ovaries**Exclusion criteria:** DiabeticsSmokersThose who used injectable hormonal contraceptive within 6 monthsThose taking sex hormones, drugs that affect gastrointestinal motility or carbohydrate metabolism, or lipid-lowering and/or anti-obesity drugs within 3 months ofthe study**N at enrollment:** **G1:** 20**G2:** 20**G3:** 20**N at followup:** **G1:** 14**G2:** 14**G3:** 14**Age, mean years ± SD:****G1:** 28.2 ± 1.1**G2:** 27.7 ± 1.3**G3:** 32.1 ± 0.7**G1 vs. G2 vs. G3:** p=NS**BMI, mean kg/m2 ± SD:****G1:** 39.9 ± 1.5**G2:** 41.3 ± 1.8**G3:** 41.2 ± 1.7**G1 vs. G2 vs. G3:** p=NS**Parity:**NR**Race, n (%):**Caucasian:**G1+G2+G3:** 40 (67)African-American: **G1+G2+G3:** 20 (33) | **Bleeding:**Cycle changes measured by menstrual frequency index,b mean ± SD: **G1:** 0.22 ± 0.04**G2:** 0.21 ± 0.04**G3**: 0.29 ± 0.04Absolute weight, mean kg ± SD:**G1:** 110.5 ± 6**G2:** 113.4 ± 7**G3:** 112 ± 8Abdominal girth, mean cm ± SD: **G1:** 120.4 ± 4.5**G2:** 123.4 ± 4.3**G3:** 122 ± 4.4BMI, mean kg/m2 ± SD: **G1:** 40.3 ± 2**G2:** 43.3 ± 2**G3:** 40.9 ± 2 | **Bleeding:**Cycle changes measured by menstrual frequency index,b mean ± SD:**G1:** 0.57 ± 0.08**G2:** 0.49 ± 0.08**G3:** 0.83 ± 0.08**G1+G2+G3 vs. BL:** p=0.0001**G3 vs. G1:** p=0.091**G3 vs. G2:** p=0.018Ovulatory rate,%:**G1:** 50**G2:** 29**G3:** 86**G3 vs. G1:** p<0.001**G3 vs. G2**: p<0.001**Weight changes:**Weight loss, mean kg ± SD:**G1:** 3.2 ± 0.1**G2:** 1.6 ± 0.2**G3:** 6 ± 0.5**G1+G2+G3 vs. BL:** p=0.001**G1 vs. G2:** p=0.019**G3 vs. G2:** p=0.003Abdominal girth, mean ± SD:**G1:** 119.6 ± 4.3**G2:** 123.9 ± 4.4**G3:** 116 ± 4.3**G1+G2+G3 vs. BL:** p=0.047**G3 vs. G2:** p=0.04BMI, mean kg/m2 ± SD: **G1:** 39.3 ± 2**G2:** 42.3 ± 2**G3:** 39.2 ± 2**G1+G2+G3 vs. BL:** p<0.0001**Quality of life:**NR**Pain:**NR**Sexual function:**NR**Patient satisfaction:**NR**Fertility:**NR**Time to conception:**NR**Additional interventions:**NR**Adverse events, n (%):**Nausea:**G1:** 3 (15)**G2:** 4 (20)**G3:** 9 (45)Diarrhea:**G1:** 0**G2:** 6 (30)**G3:** 2 (20)Bloating:**G1:** 0**G2:** 2 (10)**G3:** 1 (5)Vomiting:**G1:** 1 (5)**G2:** 1 (5)**G3:** 2 (10)Cramping (gastrointestinal):**G1:** 1 (5)**G2:** 0**G3:** 0Headache:**G1:** 1 (5)**G2:** 0**G3:** 0Indigestion/heartburn:**G1:** 0**G2:** 0**G3:** 2 (10)Stomachache:**G1:** 0**G2:** 1 (5)**G3:** 0Constipation:**G1:** 0**G2:** 1 (5)**G3:** 1 (5)Fatigue:**G1:** 0**G2:** 2 (10)**G3:** 1 (5)Dizzy:**G1:** 0**G2:** 0**G3:** 2 (10)Injection site pain/bruise:**G1:** 1 (5)**G2:** NA**G3:** 2 (10)Pregnancy:**G1:** 1 (5)**G2:** 2 (10)**G3:** 1 (5)Menstrual cramps:**G1:** 0**G2:** 1 (5)**G3:** 0Dysfunctional menstrual bleeding:**G1:** 1 (5)**G2:** 1 (5)**G3:** 0Acne:**G1:** 0**G2:** 0**G3:** 1 (5)Migraines:**G1:** 0**G2:** 1 (5)**G3:** 0Hot flashes:**G1:** 0**G2:** 1 (5)**G3:** 0 | **Overall quality:** Poor**Risk of bias:** Randomization: LowAllocation concealment:UnclearSelective reporting:LowBlinding patients/personnel:HighBlinding outcome assessment:HighIncomplete outcome reporting:HighOther:Low |

**Table Notes:** a Baseline measures for the subset of subjects who competed the trial (n=14 in each group); b Cycle event rate (normalized to 12 per 52 weeks)